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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/691,002	Applicant(s) GOWER ET AL.	
	Examiner David M. Naff	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) 40-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/22/03 & 3/11/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/1/04 & 5/12/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS 3/15/04</u> . |

5 Claims 40-76 are withdrawn from further consideration pursuant to
37 CFR 1.142(b) as being drawn to a nonelected invention, there being
no allowable generic or linking claim. Election was made **without**
traverse in the reply filed on 4/20/06.

10 *Specification*

Appropriate correction is required.

Claim Rejections - 35 USC § 112

20 112:

25 Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph,
as being indefinite for failing to particularly point out and

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distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear by claim 1 claiming the composite in terms of how it is made, i.e. the mineral phase being deposited on the matrix in the form of a mineral precursor, and not setting forth clear, distinct and positive process steps.

In lines 2 and 4 of claim 1 and where recited in other claims "inorganic mineral phase" and "liquid phase mineral precursor", respectively, are uncertain as to meaning and scope. It is uncertain as to material that is the mineral phase and material that is the mineral precursor, and how the mineral phase and mineral precursor differ from each other.

Claim 1 in the penultimate line is unclear as to physical phenomena that constitutes the inorganic mineral phase being aligned along the long axis of the fibers of the fluid-swellaable, fibrous matrix. The mineral phase has not been required to have a structural relationship to the fibrous matrix that can result in alignment as claimed. When a mineral phase having no structure is deposited on and within the fibrous matrix as required in lines 2 and 3, it is not seen how there can be alignment of the mineral phase with a long axis of fibers contained by the fibrous matrix? How would one know when such alignment occurs?

Claim 1 is confusing by not having clear antecedent basis for "the long axis of each of the fibers" in the penultimate line. To provide antecedent basis, it is suggested the claim be amended in line

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4 after "wherein" by inserting --- the fibrous matrix contains fibers having a long axis and ---.

In line 2 of claim 5, "non-faceted topography" is uncertain as to meaning and scope. The physical feature that is a non-faceted
5 topography is uncertain.

In line 2 of claim 6 and where recited in other claims, "[001]" is uncertain as to purpose in the claim, and how this defines the invention.

Claims 6, 17 and 18 are unclear as to physical phenomena that
10 constitutes hydroxyapatite crystals oriented in the direction along the long axis of the fibers since the crystals have not been required to have a structure that can be oriented as claimed. How would one know when the crystals are oriented as claimed?

Claims 6, 16, 17 and 18 are unclear as to material that is a
15 mineral precursor when the mineral phase contains hydroxyapatite crystals.

Claim 7 is unclear by requiring the inorganic mineral phase to have an amorphous morphology or crystalline morphology since the phase has not been required to have a physical form that can have the
20 morphology claimed.

Claim 8 is unclear by requiring elastin, chitin, cellulose, chitosan or peptide nanofibers to be the fibrous matrix since each of these materials has not been established to be composed of fibers having a long axis. The meaning of "peptide nanofibers" is uncertain
25 since this is not appear to be an art recognized term.

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In claims 9 and 14, a change in the surface that is "surfaced-modified" is uncertain. Being "surfaced-modified" is relative and subjective. Additionally, the claims are unclear as to whether the fibers are "surfaced-modified" before or after the mineral phase is deposited.

In claim 10, "ion implantation", "grafting", "photopolymerization" and "adsorption" are unclear to method used for surface modification.

In claim 12, "collagen type 7", "collagen type 9", "collagen type 10", "collagen type 12", "collagen type 13", "collagen type 14", "collagen type 16", "collagen type 17" and "collagen type 19" are unclear as to the collagen type required since these collagen types are not art recognized as being types of collagen. If publications are available reciting these types of collagen, copies should be provided.

In claims 13 and 18, the meaning of "abutting fibrils" is uncertain.

Claim 19 is unclear as to the relationship of the biologically active agent to the composite. Where does the composite contain the agent? Additionally, is the agent added before or after the mineral phase is deposited?

In claim 20, "prevention, diagnosis, cure or mitigations of disease or illness" are not biologically active agents as required by the claim.

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Claims 22 and 23 are unclear as to how the mineral phase can have pendantly attached and embedded active agents, respectively, since the minerals have not been required to be in a form for the agents to be pendantly attached or embedded.

5 In line 4 of claim 26, there is not clear antecedent basis for "the organic matrix".

In claim 30, there is not clear antecedent basis for "the microporosity". Additionally, it is uncertain as to how "supercritical processing" and "molecular compounds" provide
10 microporosity.

Claim 31 fails to have clear antecedent basis for "said organic substrate".

Claim 32 is unclear as to when the matrix of the composite is a scaffold seeded with cells, i.e. before or after the inorganic mineral
15 phase is deposited on and absorbed within the matrix.

Claim 35 fails to have clear antecedent basis for "said organic substrates". Additionally, the form of the substrates when arranged in the form of lamellae is unclear.

In claim 36, "osteon-like structure" is uncertain as to meaning
20 and scope. Being "like" osteon is relative and subjective.

Claim 37 is unclear as to whether the plurality of matrices with an adhesive layer between each of the matrices occurs before or after the mineral phase is deposited.

Claims 38 and 39 fail to have clear antecedent basis for "said
25 plurality of organic substrates".

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Claim 38 is unclear by requiring substrates oriented parallel since the substrates have not been required to have structure that can be oriented parallel.

Claim 39 is unclear as to form of the substrates when having an alternating orientation since the claim fails to specify material the substrates alternate with.

Claim Rejections - 35 USC § 102

Claims 1-5, 7, 8, 11-13, 15, 24-29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Olszta (Biomimetic Mineralization of Type-I Collagen) (R9 on 1449 of 5/12/04) or Olszta (Biomimetic Mineralization of Type-I Collagen) (R11 on 1449 of 5/12/04) or Olszta (Biomimetic Mineralization of Collagen for Nanostructured Composites (R27 on 1449 of 3/15/04)).

The claims are drawn to an organic/inorganic composite comprising and organic fluid-swellable fibrous matrix and an inorganic mineral phase, wherein the mineral phase is deposited on and within the matrix from a liquid phase mineral precursor, and wherein the mineral phase is aligned along the long axis of each of the fibers of the matrix.

Olszta R9, R11 or R27 disclose mineralization of collagen by preparing a calcium chloride solution, addition of short chain acidic polymers (poly-L-aspartic acid and polyacrylic acid), addition of a collagen substrate, and vapor diffusion of ammonium carbonate. For example, see the 5th page of R9 and R27, and pages 15 and 16 of R11.

The mineralization of collagen as disclosed by Olszta R9, R11 or R27 produces a composite that is the same as presently claimed. The

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composite produced by Olszta R9, R11 or R27 inherently has a mineral phase aligned along the long axis of each fiber of collagen. The calcium chloride solution, acidic polymer and ammonium carbonate form a mineral precursor. The features of dependent claims are inherently
5 contained by the composite produced as disclosed by Olszta R9, R11 or R27.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was
15 made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering
20 patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation
under 37 CFR 1.56 to point out the inventor and invention dates of
25 each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 6, 16, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Silver et al (5,532,217).

Claims 6 and 16 require hydroxyapatite as the mineral and claims 5 17 and 18 require hydroxyapatite crystals oriented along the long axis of the fibers.

Silver et al disclose mineralization of collagen fibers with hydroxyapatite. For example, see claim 8, col 4.

It would have been obvious to carry out the mineralization of 10 Olszta R9, R11 or R27 with hydroxyapatite as suggested by Silver et al since hydroxyapatite contains calcium phosphate which Olszta R9, R11 or R27 can use for mineralization. Crystals of hydroxyapatite will inherently be formed and oriented as claimed.

Claim Rejections - 35 USC § 103

15 Claims 9, 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Rhee et al (5,800,541).

The claims require the matrix to be surface-modified.

Rhee et al disclose modifying collagen to bind biological agents 20 to a collagen-synthetic polymer matrix for use as an implant (paragraph bridging cols 17 and 18, and col 18, lines 20-50).

It would have been obvious to modify the collagen of the composite of Olszta R9, R11 or R27 as suggested by Rhee et al to bind biological agents.

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Claim Rejections - 35 USC § 103

Claims 19-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Liu (6,300,315 B1).

The claims require the composite to contain a biologically active agent.

Liu discloses producing a mineralized collagen membrane by adding calcium and phosphate ions to a collagen slurry (col 2, line 53 to col 3, line 21) to form precipitated calcium phosphate. A drug may be incorporated in the membrane (col 3, lines 57-65). Drugs include antibiotics, bone morphogenetic proteins, bone growth factors, skin growth factors, antiscarring agents and/or mixtures.

It would have been obvious to incorporate a biologically active agent when preparing the composite of Olszta R9, R11 or R27 to obtain the function of the agent as suggested by Liu incorporating a drug that is a biologically active agent in a mineralized collagen membrane.

Claim Rejections - 35 USC § 103

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 19-21 and 23 above, and further in view of Rhee et al.

The claims requires the biologically agent to be pendantly attached to the matrix.

Rhee et al is described above.

When incorporating a biologically active agent as suggested by Liu as above, it would have been obvious to attach the biologically

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active agent pendantly to a reactive group formed on the collagen of Olszta R9, R11 or R27 as suggested by Rhee et al rather than incorporating the agent in the collagen.

Claim Rejections - 35 USC § 103

5 Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Brown et al (6,201,039 B1).

The claim requires pores to be formed in the matrix by methods that include freeze-drying.

10 Brown et al disclose obtaining a porous collagen matrix by a method involving freeze-drying (col 10, lines 14-20).

It would have been obvious to make the collagen of Olszta R9, R11 or R27 porous by using freeze-drying as suggested by Brown et al.

Claim Rejections - 35 USC § 103

15 Claims 32, 33, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Connelly et al (6,995,013 B2).

Claims 32 and 33 require the matrix to be a scaffold seeded with cells. Claims 35 and 36 require the composite to be in the form of a lamellae and an osteon-like structure, respectively.

20 Connelly et al disclose using collagen to form a cell-scaffold having five layers (col 13, lines 38-42) for producing tissue, and that bone structure contains osteons formed of lamellae (col 2, lines 24-37).

25 It would have been obvious to seed the collagen of Olszta R9, R11 or R27 with cells as suggested by Connelly et al to form tissue. It

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would have been further obvious to form the collagen of Olszta R9, R11 or R27 in the form of osteons containing lamellae to simulate the natural structure of bone as suggested by Connelly et al.

Claim Rejections - 35 USC § 103

5 Claims 34 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olszta R9, R11 or R27 in view of Song et al (5,418,222).

 Claim 34 requires the matrix to be a film. Claims 37-39 require a plurality of matrices having an adhesive layer between each matrix.

10 Song et al disclose a multiple layer collagen film having an adhesive between each layer for delivery of pharmaceuticals (col 5, lines 58-61).

 It would have been obvious to provide the collagen of Olszta R9, R11 or R27 as a multiple layer film and adhere the layers together
15 with an adhesive as suggested by Song et al when desiring the function of a multiple layer film. The layers of Song et al are parallel as required by claim 38, and providing an alternating orientation as in claim 39 would have been obvious for putting a different pharmaceutical in each layer.

20

Conclusion

 Any inquiry concerning this communication or earlier
communications from the examiner should be directed to David M. Naff
whose telephone number is 571-272-0920. The examiner can normally be
25 reached on Monday-Friday 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

5 Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For
10 more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

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DMN
7/17/06